



June 1, 2005

1754 5 JUN 22 P2:20

Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

JUN -8 2005

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: Muscular / Skeletal Health, Women's Health

Dietary Ingredients: Vitamin D3 (as Cholecalciferol), Vitamin K (as Phytonadione), Folic Acid, Calcium (as Hydroxyapatite, Citrimal), Phosphorus (as Chelate), Magnesium (as Buffered Amino Acid Chelate, Citrate), Selenium (as Amino Acid Complex), Copper (as Lysinate), Manganese (as Chelazome), Molybdenum (as Amino Acid Chelate), Ipriflavone, Strontium Citrate, Montmorillonite, Boron (as Proteinate), Natural vegetable capsules, Turmeric Root Extract, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: OsteoPrev

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager
Document Control / Training Manager
Ortho Molecular Products

97S 0162

LET

16290

Ortho Molecular Products OsteoPrev
6/1/2005
Page 1 of 2



Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Attachment of OsteoPrev Labels

Suggested Use: As a dietary supplement, 4 capsules per day or as recommended by your health care professional.
Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors.
If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.
KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE.
KEEP OUT OF REACH OF CHILDREN.
Chelazome® and Citrimat® are registered trademarks of Albion, Inc.
This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal is missing or damaged.
† This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Label ID: L-CMP100-567120-D



Also Excellent for:



OsteoPrev

Supplement Facts		
Serving Size 4 Capsules		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value
4 capsules contain		
Vitamin D3 (as Cholecalciferol)	1000 IU	250%
Vitamin K (as Phytonadione)	1 mg	1250%
Folic Acid	600 mcg	200%
Calcium	200 mg	20%
(as Hydroxapatite, Citrimat®)		
Phosphorus (as Chelate)	15 mg	2%
Magnesium (as Buffered)	150 mg	38%
Amino Acid Chelate, Citrate		
Selenium	200 mcg	286%
(as Amino Acid Complex)		
Copper (as Lysinate)	1 mg	50%
Manganese (as Chelazome®)	10 mg	500%
Molybdenum (as Amino Acid Chelate)	150 mcg	200%
Ipriflavone	600 mg	*
Strontium Citrate	200 mg	*
Montmorillonite	150 mg	*
Boron (as Boronate)	5 mg	*
* % Daily Value not established		

Other Ingredients: Natural vegetable capsules and Turmeric Root Extract. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.

Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive, Stevens Point, WI 54481

OrthoMolecularProducts.com

Dietary Supplement Product #567

120 Capsules

Ortho Molecular Products OsteoPrev

6/1/2005

Page 2 of 2